(12) UK Patent Application (19) GB (11) 2 130 093 A

(21) Application No 8327439
(22) Date of filing 13 Oct 1983
(30) Priority data
(31) 8229455
8308576
(32) 14 Oct 1982
29 Mar 1983
(33) United Kingdom (GB)
(43) Application published
31 May 1984
(51) INT CL³
A61M 29/02
(52) Domestic classification
A5R GA
(56) Documents cited
None
(58) Field of search
A5R

(71) Applicant
Matburn (Holdings) Limited
(United Kingdom),
Clarges House, 6/12
Clarges Street, London
W1Y 8DH

(72) Inventors
Kenneth John Brooks,
Michael Anthony Wilkinson,
Peter Henry Hannam,
Neil Adrian Whiteside

(74) Agent and/or Address for Service
Elkington & Fife,
High Holborn House,
52/54 High Holborn,
London WC1V 6SH

(54) Dilatation catheter

(57) A dilatation catheter has a shaft (S) comprising a tube (1) of braided material encapsulated over a major portion of its length in an outer coating (2) of semi-rigid inelastic material. An outer coating (3) of elastic material extends over a minor portion of the length of the shaft at or near its distal end. An inner coating (4) of elastic material may be provided over the entire length of the inside of the tube (1). The distal end portion of the catheter is inflatable by pressure applied from within the shaft to form a balloon. Radio-opaque markers (5*a* and 5*b*) may be provided at each end of the inflatable portion.

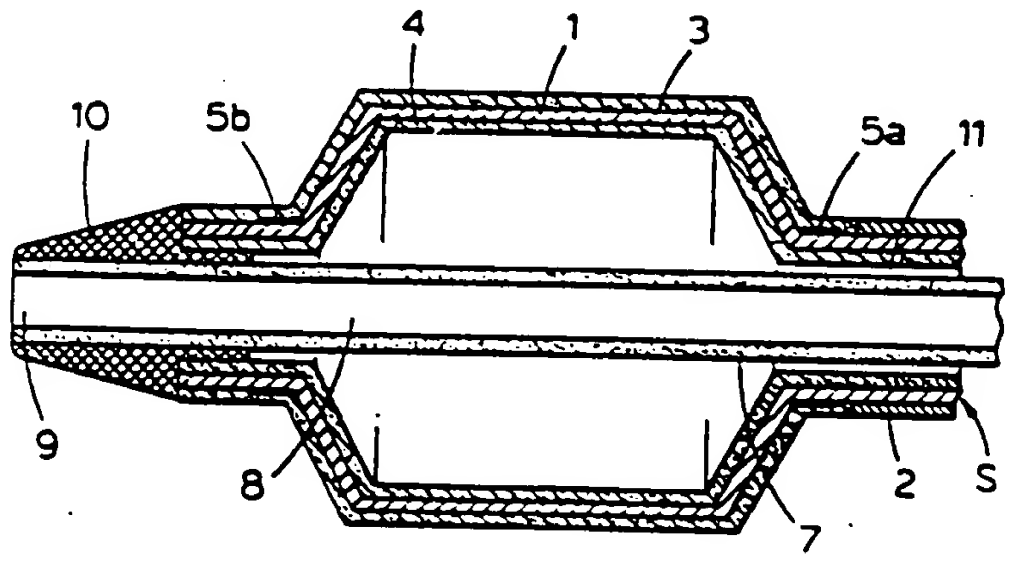

Fig.3

GB 2 130 093 A

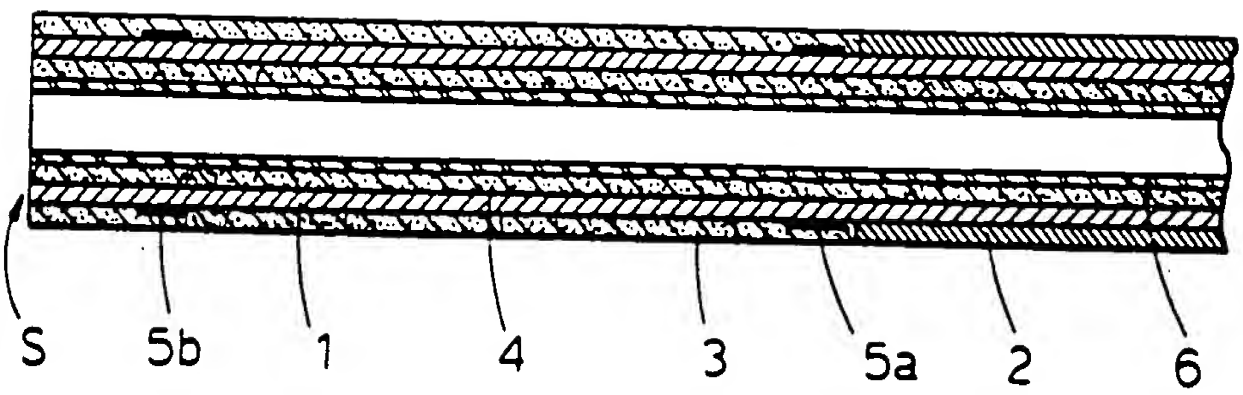

Fig.1

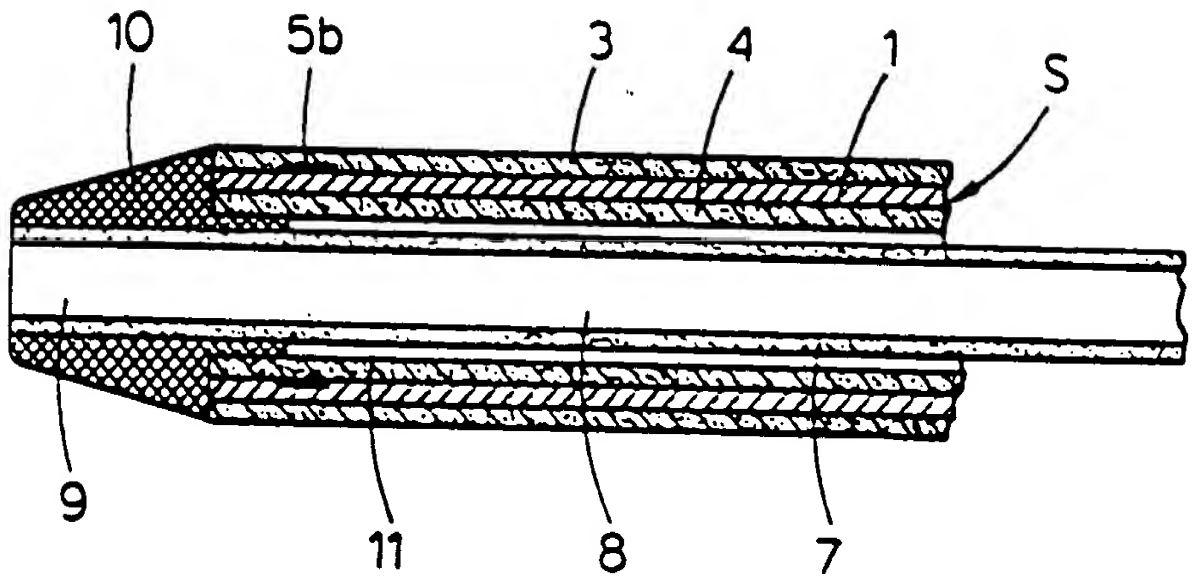

Fig.2

2130693

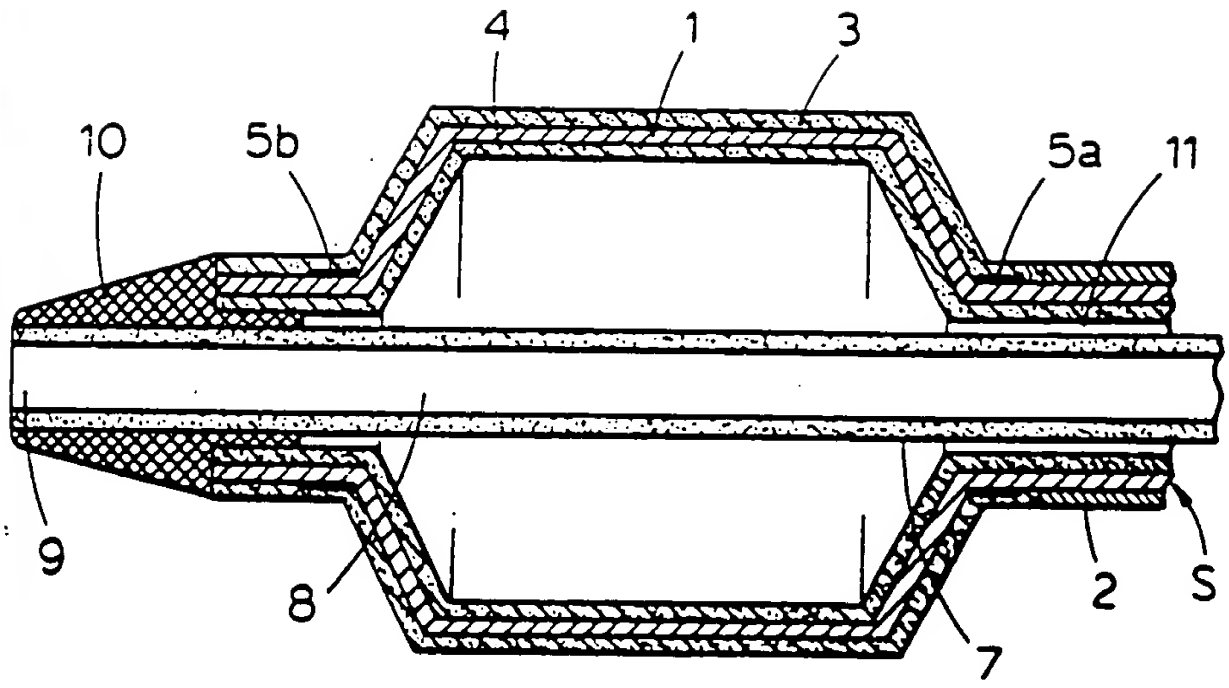

Fig.3

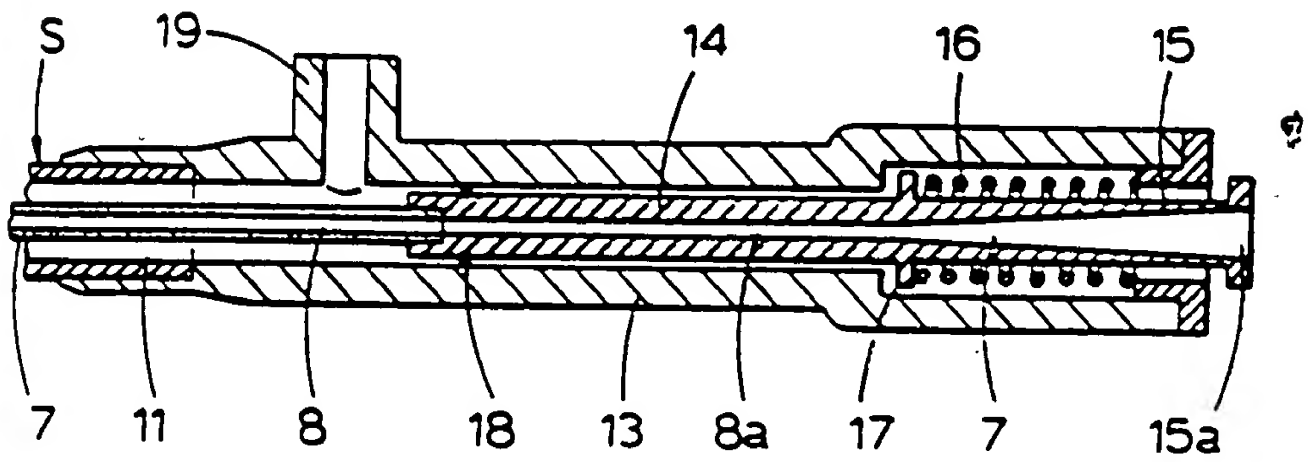

Fig. 4

SPECIFICATION
Catheters

This invention relates to dilatation catheters.

Such catheters are well known. They are commonly used for example, in angioplasty procedures to dilate blood vessels. They comprise a catheter shaft with an inflatable balloon located near the leading end of the catheter when it is inserted into the body of the patient. This end is commonly known as the distal end. This balloon is inflated in order to effect the desired dilatation of the blood vessel. When this procedure is completed, the balloon is deflated and the catheter is removed from the body. Hitherto, the balloon of such a catheter has consisted of an inflatable sleeve or bulb fitted on the outside of the shaft at or near the distal end. The balloon is inflated by the application of fluid passing from within the shaft. It is obviously desirable that the balloon does not inflate to an extent which would damage the blood vessel of the patient and it is an object of the present invention to provide a dilatation catheter with an inflatable portion or balloon which cannot expand beyond acceptable limits and which, when the inflatable portion is deflated, has a smooth surface flush with the shaft. Accordingly, the present invention provides a dilatation catheter in which a shaft of the catheter comprises a tube of braided material having an inelastic outer coating of semi-rigid material extending from a proximal end of the catheter over a major portion of the length of the shaft and also having an elastic outer coating extending over a minor portion of the length of the shaft at or near the distal end of the catheter whereby the said minor portion is inflatable. If desired, the portion of the braided tube covered by the elastic coating may have a more open form, that is to say, it has fewer picks per unit length, to improve inflation. With this arrangement, the outer surface of the catheter is smooth over its entire length and the inflatable portion can be inflated to a predetermined diameter.

For convenience of description, the inflatable portion of the catheter is, where its context so permits, hereinafter referred to as a "balloon".

The catheter of the present invention preferably includes an inner tube defining a central lumen opening at both ends of the catheter. This allows the catheter to be passed over a guide wire during insertion and provides a means of pressure monitoring and fluid injection. The annular space between the inner tube and outer shaft of the catheter forms a passage through which an inflation fluid can pass in order to inflate the balloon. The inner tube is axially displaceable with respect to the outer shaft to accommodate its movement during inflation.

Some embodiments of the invention are illustrated in the accompanying drawings of which:

Figure 1 is a schematic sectional view of a distal end portion of a dilatation catheter, showing a balloon portion in a deflated condition.

Figures 2 and 3 are schematic sectional views of the distal end portion of a modified catheter according to this invention, also respectively illustrating the catheter in the deflated and inflated condition, and

Figure 4 is a schematic cross-sectional view through a mount attached to the proximal end of the catheter.

In the embodiment of the invention illustrated in Figure 1, dilatation catheter comprises a shaft generally designated S and composed of a tube 1 of braided material which may conveniently be a polyester fibre. A major part of the outer surface of the braided tube 1 is encapsulated within a coating 2 of a semi-rigid, inelastic material preferably a plastics material such as semi-rigid polyurethane or another semi-rigid plastics material such as polyvinylchloride (PVC) or polyethylene. The inelastic plastics coating 2 is interrupted near the distal end of the catheter and this interrupted minor portion is itself encapsulated within a coating 3 of an elastic material which may be an elastic polyurethane or another elastomeric material, such as silicone rubber. The elastic coating 3 is flush with the inelastic coating 2 so that the cross-sectional area of both the major portion and the minor portion are the same with the result that the profile or outer surface of the shaft is smooth, that is to say uniform, over its entire length, except for a tip at the distal end. The portion of the braided tube encapsulated by the elastic coating 3 preferably has a more open form, that is to say fewer picks per unit length are present than the number of picks per unit length present in the major portion of the tube 1. This makes this portion of the catheter more readily inflatable than would otherwise be the case. The portion of braided tube immediately distal to the balloon may have a less open form similar to the major portion of the braided tube to limit inflation or alternatively a rigid sleeve could be positioned at this point for the same purpose. An inner coating 4 of the same or similar elastic material as the outer coating 3 is preferably bonded to the inside of the braided tube over the entire length of the catheter. A radio-opaque marker portion 5*a* is incorporated in the shaft at or near the junction between the two outer coatings 2 and 3. Another such marker 5*b* is provided near the distal end of the shaft. A lining 6 may be provided. This lining may extend the entire length of the shaft as illustrated or the portion of the shaft having the balloon coating 3 need not be lined. The material of the lining may be a fluorocarbon such as polytetrafluoroethylene (PTFE) or fluorinated ethylene propylene copolymer (FEP).

As shown in Figures 2, 3 and 4, an inner tube 7, is arranged inside the shaft S. The inner tube 7 is of a semi-rigid material such as PVC. It is coaxial with the shaft S and is axially displaceable with respect to it. This tube 7 defines a central lumen 8 having an opening 9 at its distal end. If desired a lining (not shown) corresponding to the lining 6 of the Figure 1 embodiment may be bonded to the

coating 4 to reduce friction. The inner tube 7 is secured to the outer shaft S by means of a tip or plug 10 at the distal end of the catheter although, as previously stated, the tube 7 is axially displaceable with respect to the outer shaft S. As shown in Figures 2 and 3, the tip 10 tapers towards the distal end of the catheter. In addition to defining the central lumen 8, the inner tube 7 also defines an outer annular lumen 11 which serves as an inflation lumen through which fluid can pass to inflate the balloon portion of the catheter. The tip 10 also serves as a seal for the inflation lumen 11. The radio-opaque marker 5*b* is positioned at the distal extremity of the balloon.

A mount is provided at the proximal end of the catheter as shown in Figure 4. This mount comprises a rigid or semi-rigid body 13 of metal or of plastics material secured to the outer coating of the shaft S. An inner piston member 14 is located inside the body and is bonded to the outside of the inner tube 7. The piston member 14 has a central passage 8*a* communicating with the central lumen 8 of the inner tube 7 so that liquid may be introduced to the lumen 8 via an opening 15*a* of a luer mount 15 or the like at the proximal end of the passage 8*a*. The liquid can flow through the lumen 8 and exit through the opening 9 at the distal end and then enter the patient. The passage 8*a* and lumen 8 also allows pressure monitoring to be carried out during the procedure and provides a means of inserting the catheter over a guide wire. A coil spring 16 surrounds the piston member inside the body and bears on a shoulder 17 of the piston member to urge it towards the distal end of the catheter. Means may also be provided to prevent the piston member 14 rotating with respect to the body 13. A flexible seal 18 seals the annular passage between the body 13 and the piston 14 and, therefore, the proximal end of the annular lumen 11.

A luer mount 19 or other suitable connection extends laterally from the body 13 and communicates with the interior of the body so that fluid can be passed into the outer annular lumen 11 of the catheter to enable the balloon portion to be inflated.

In use, the catheter may be inserted over a previously inserted guide wire into a blood vessel of a patient to be treated. The guide wire may then be removed. The balloon portion of the catheter is inflated by fluid pressure, conveniently produced by a suitable syringe. When the procedure has been completed, the fluid pressure is removed so that the balloon portion cann resume its initial shape. When the fluid pressure has been removed, the piston member 14 will move towards the distal tip 10 assisted by the coil spring 16 to displace the inner tube 7 in the same direction to assist in returning the inflatable balloon portion to its non-inflated configuration as quickly as possible. Such movement also overcomes any residual tension set in the balloon portion of the catheter.

The catheter may conveniently be produced by a method in which the tube 1 is made by braiding around a suitable former. The former is previously provided with the inner coating 4. The X-ray opaque members 5*a* and 5*b* are then positioned. The outer coating 3 is provided and penetrates the braid and forms a bond with the inner coating 4. The outer coating 2 is then applied to the major portion of the tube 1. The inner tube 7 and outer shaft S are secured to the piston member 14 and body 13 respectively. The distal tip 10 is then fitted.

The catheter of this invention may be modified for uses other than angioplasty procedures, but where dilatation is still required. In a modified catheter intended for general dilatation purposes, the catheter does not have an inner tube and the distal tip of the catheter is completely sealed. The proximal mount illustrated in Figure 4 is not required in this modification but a luer mount with an integral stop-cock may be provided at the proximal end of the catheter to permit inflation fluid to be supplied to the catheter.

CLAIMS

1. A dilatation catheter wherein a shaft of the catheter comprises a tube of braided material having an inelastic coating of semi-rigid material extending from the proximal end of the catheter over a major portion of the length of the shaft and also having an elastic outer coating extending over a minor portion of the length of the shaft at or near the distal end of the catheter whereby the said minor portion is inflatable.

2. A catheter as claimed in claim 1 wherein the cross-sectional area of both the major portion and the inflatable minor portion are the same whereby the profile of the catheter shaft is uniform over its entire length except for a tip at the distal end.

3. A catheter as claimed in claim 2 wherein the tip tapers towards the distal end.

4. A catheter as claimed in any preceding claim wherein an inner tube which is open at both ends of the catheter extends through the shaft thereby to define a central lumen and an outer annular lumen, means communicating with the annular lumen being provided to enable a fluid for inflating the said minor portion to be supplied to the annular lumen.

5. A catheter as claimed in claim 4 wherein the inner tube is displaceable axially with respect to the shaft.

6. A catheter as claimed in any one of the preceding claims wherein the tube of braided material is provided with an inner coating of elastic material extending the entire length of the catheter.

7. A catheter as claimed in any one of claims 1 to 6 wherein the braided material has a more open form over the portion of its length within the minor portion having the elastic outer coating.

8. A catheter according to any preceding claim wherein a radio-opaque marker is arranged between the tube of braided material and the outer coating.

9. A catheter according to any preceding claim

wherein radio-opaque markers are provided at each end of the inflatable portion.

10. A catheter according to any one of claims 4 to 9 wherein a tip is secured to the outer shaft internally of the distal end thereof, the inner tube being also engaged in the tip.

11. A catheter according to any one of claims 4 to 10 wherein a mount is fitted at the proximal end of the shaft, the said mount comprising a body secured to the shaft; a piston member is arranged inside the body and is secured to the inner tube of the shaft, the said piston member having a passage through which liquid can pass to or from the inner tube; spring means for urging the piston member towards the distal end of the shaft; a flexible seal between the piston and the body and a connection leading through the body to the annular lumen to permit inflation fluid to be supplied to the annular lumen whereby the catheter can be inflated over the said minor portion.

12. A catheter according to claim 1 wherein the piston member is fixed against rotation with respect to the body.

13. A dilatation catheter substantially as described with reference to Figure 1 of the accompanying drawings.

14. A dilatation catheter substantially as described with reference to Figures 2—4 of the accompanying drawings.

Printed for Her Majesty's Stationery Office by the Courier Press, Leamington Spa, 1984. Published by the Patent Office, 25 Southampton Buildings, London, WC2A 1AY, from which copies may be obtained.